

# Extragenital Chlamydia/Gonorrhea NAAT Screening at Local Health Department Clinics



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## Revision History

[illegible]

## Purpose

This document is written for non-laboratory personnel responsible for the collection and transport of rectal and pharyngeal swab specimens for chlamydia/gonorrhea (CT/GC) nucleic acid amplification testing (NAAT) screening. Specimen analysis, outcome, diagnosis, and therapeutic decisions are highly sensitive to deviations in collection method, container, transportation, and storage; therefore, all personnel in contact with specimens must ensure the proper collection, preparation, and transportation of specimens to the laboratory.

NAAT testing represents a significant advancement in CT/GC screening as previously culture, a test with comparatively poor sensitivity, was required to diagnose. FDA approval for this test is limited to genital specimens; however, research demonstrates the CT/GC NAAT is acceptable for testing extragenital specimens. Because this use of the CT/GC NAAT test is not FDA approved, each laboratory must conduct analytical validation of their methodology. Virginia's public health laboratory, the Division of Consolidated Laboratory Services (DCLS), can only conduct culture testing for extragenital specimens. LabCorp completed validation for extragenital NAAT and, per state contract, provides diagnostic testing for local health departments.

Extragenital screening is critically important, particularly among some high-risk populations: **77% of CT and 95% of GC infections are missed** among men who have sex with men (MSM) if screening is only performed at urethral sites.<sup>1</sup> Symptoms of rectal and pharyngeal CT/GC are nonspecific and often silent. In fact, 85% of rectal CT/GC infections are asymptomatic in MSM.<sup>2</sup> Self-collection, particularly for rectal specimens, increases the uptake of testing and offers high acceptance among MSM; self-collection can eliminate access barriers such as stigma, shame, negative interactions with service providers, and concerns about privacy and confidentiality. Published clinical research indicates self-collected specimens have equivalent or better detection rates for rectal and pharyngeal CT/GC compared to clinician collection.<sup>3,4</sup>

## Supply Ordering

The Aptima Combo 2 Assay Unisex Swab Specimen Collection Kit (Figure 1) is used for rectal and pharyngeal specimen collection. This is the same collection kit used for male urethral and female endocervical swabs. The **blue handled swab** must be used for collection. Once the kit has been opened, the white handled swab should be discarded (specimens sent using the white handled swab will be rejected). The white handled swab is included for use in endocervical collection.

To order collection kits, send the following information to applicable LabCorp account representative for your health district: organization name, your name, contact information, shipping address, and quantity of kits needed. If the local agency conducts other laboratory testing through LabCorp, follow local procedures.

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<sup>1</sup> Marcus JL, Bernstein KT, Kohn RP, et al. Infections missed by urethral-only screening for chlamydia or gonorrhea detection among men who have sex with men. *Sex Transm Dis*. 2011;38:922-924.

<sup>2</sup> Kent CK, Chaw JK, Wong W, et al. Prevalence of rectal, urethral, and pharyngeal chlamydia and gonorrhea detected in 2 clinical settings among men who have sex with men: San Francisco, California, 2003. *Clin Infect Dis*. 2005;41:67-74.

<sup>3</sup> van der Helm JJ, Hoebe CJ, van Rooijen MS, et al. High performance and acceptability of self-collected rectal swabs for diagnosis of *Chlamydia trachomatis* and *Neisseria gonorrhoeae* in men who have sex with men and women. *Sex Transm Dis*. 2009;36:493-497.

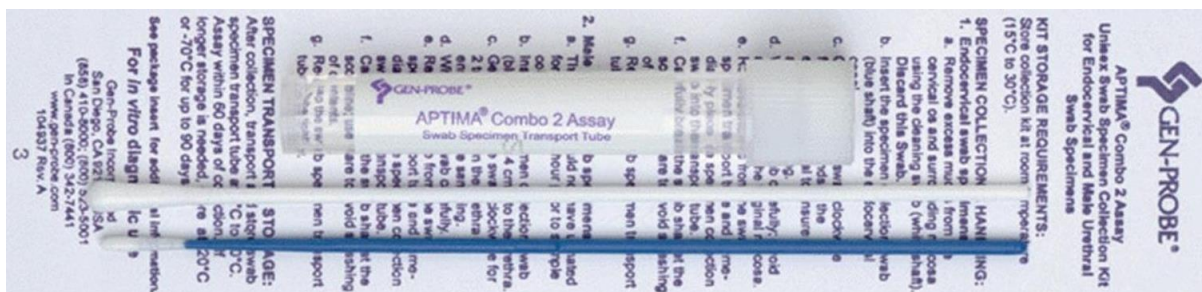
<sup>4</sup> Lunny C, Taylor D, Hoang L, et al. Self-collected versus clinician-collected sampling for chlamydia and gonorrhea screening: A systematic review and meta-analysis. *PLoS ONE*. 2015;10:1-23.

## Eligibility

A thorough sexual history should be obtained by the clinician. CT/GC screening should be informed by client-reported exposure, regardless of condom use. Specimens for screening may be obtained for any, or all, of the following anatomical sites: genital (urethral, penile, vaginal/endocervical), pharyngeal, and/or rectal. Ascertaining specific sexual activities and recent partners during the sexual health history will guide clinical decisions. For example, a patient who has receptive anal and oral sex with the same partner, reporting no other partners, may only need a rectal screening since both anatomical sites have identical exposure. If, however, a patient indicates receptive anal sex with one partner, but only oral sex with another then both sites should be screened.

A period of four weeks must elapse between a positive screening test or treatment for CT/GC and a subsequent test for re-exposure, regardless of the anatomical site. This is due to the high sensitivity of the test.

**Figure 1: Aptima Combo 2 Assay Unisex Swab Specimen Collection Kit**



## Collection Procedures and Handling

- Affix a sticker label to the specimen collection tube with the following information:
  - Name (must be an exact match to the lab requisition);
  - Date of birth;
  - Date of specimen collection;
  - Specimen type (rectal/pharyngeal);
  - LabCorp test number; and
  - Additional patient identifier, if available (e.g., WebVision number).
- Do not cover the expiration date on the specimen collection tube with the sticker label.
- Collected specimens in the specimen collection tube can be stored at room temperature (2°C to 27°C) for up to 30 days.

LabCorp test numbers (at the time of developing this manual):

- Urogenital: 183194
- Pharyngeal: 188698
- Rectal: 188672

The LabCorp test number corresponds with the following WebVision codes:

- L188698 CT/GC (throat-LabCorp)
- L188672 CT/GC (rectum-LabCorp)

### Rectal Specimen Collection

- Review the collection process with the client and instruct them to collect the rectal specimen, put the swab inside the specimen collection tube, align score line with the top edge of the tube, carefully break the swab shaft, seal the tube, and return the sealed tube.
- Diagram ([Attachment A, C](#)) may be posted for patient reference.
- Visually inspect the swab to assure there is evidence of use and the swab is not contaminated with significant fecal matter, the preservative liquid is still in the tube, and the lid on the specimen collection tube is tight to prevent spillage.
- Clinicians may collect a specimen during physical exam in lieu of self-collection, if desired.

### Pharyngeal Specimen Collection

- Given adequate instruction, self-collection of a pharyngeal specimen is equivalent to, or better than, clinician collection.<sup>5,6</sup> The swab should make contact with the key areas of the throat: uvula and left/right posterior walls and tonsils.<sup>7</sup> A diagram ([Attachment B, C](#)) to guide self-collection is included for patient reference.
- Recent experience in a northern Virginia STD clinic, found patients preferred clinician collection. The same collection technique of making contact with the key areas of the throat: uvula and left/right posterior walls and tonsils should be observed.
- An instructional video is available at: <https://www.youtube.com/watch?v=KJtqxvAstCo>

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<sup>5</sup> Sexton ME, Baker JJ, Nakagawa K, et al. How reliable is self-testing for gonorrhea and chlamydia among men who have sex with men? *J Fam Pract.* 2013;62:70-78.




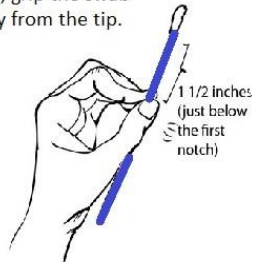

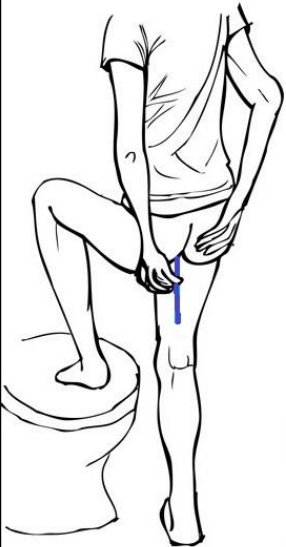

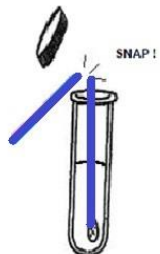


<sup>6</sup> Freeman AH, Bernstein KT, Kohn RP, et al. Swabs for the detection of *Chlamydia trachomatis* and *Neisseria gonorrhoeae* pharyngeal infection among men who have sex with men. *Sex Transm Dis.* 2011;38:1036-1039.

<sup>7</sup> San Francisco City Clinic. Patient instructions for self-collected specimens: pharyngeal and rectal. Available at: <http://www.sfcityclinic.org/providers>. Accessed December 15, 2011.

## Attachment A – Self Collection of Rectal Swab

### Self-Collection of Rectal Swab ATTENTION: Read ALL instructions before you begin!



<p><b>STEP 1</b> Wash your hands thoroughly.</p>  <p><b>STEP 2</b> Open the wrapper and remove the swab with the blue handle.</p>  <p>Do NOT touch the tip of the swab.</p>	<p><b>STEP 3</b></p>  <p>Pull underwear down or off. Squat down, or lift one leg up on a ledge, toilet, or chair.</p>	<p><b>STEP 4</b></p> <p>With one hand, grip the swab 1.5 inches away from the tip.</p>  <p>1 1/2 inches (just below the first notch)</p> <p>Do NOT use any kind of lubricant (soap, saliva, etc) on either the swab or your body.</p>	<p><b>STEP 5</b></p> <p>Use your other hand to lift one cheek for easy access to the rectum.</p> 
 <p><b>STEP 6</b> Insert the swab 1.5 inches into your rectum until you feel your fingers touch your anus.</p> <p><b>STEP 7</b> Once the swab is in, walk your fingers halfway down the swab (away from your body) and grip it there for stability.</p> <p><b>STEP 8</b> Gently turn the swab in circles for approximately 30 seconds.</p> <p><b>STEP 9</b> When removing the swab from your rectum, slowly turn it in a circle while pulling it out.</p>	<p><b>STEP 10</b> Uncap tube and keep upright - do not pour out the clear liquid. Place the swab into the tube.</p>  <p><b>STEP 11</b> Align the score line with the top edge of the tube and carefully break the shaft of the swab.</p>  <p>SNAP!</p>	<p><b>STEP 12</b> Swab will drop to the bottom of the tube. Screw cap on tightly so it doesn't leak.</p>  <p><b>STEP 13</b> Wash your hands thoroughly.</p>  <p><b>STEP 14</b> Return the tube to your health care provider.</p>	



## Attachment B – Self Collection of Pharyngeal Swab

### Self-Collection of Pharyngeal Swab

Attention: Read ALL instructions before you begin!

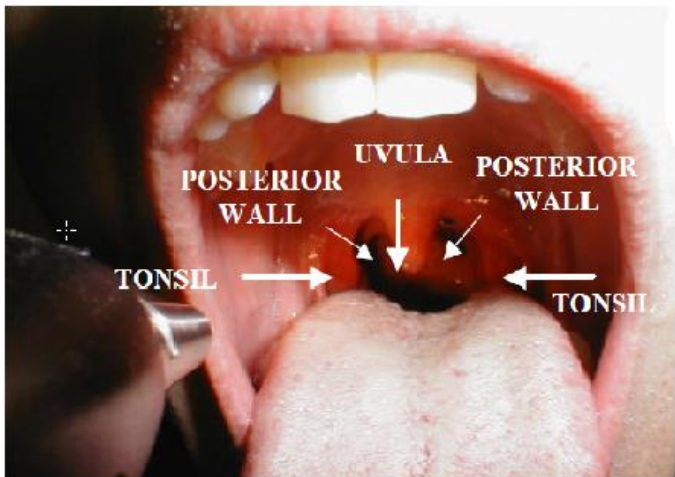
#### Step 1.



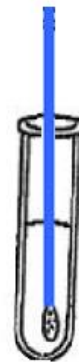
**Step 2.** Open the wrapper and remove the swab with the blue handle.



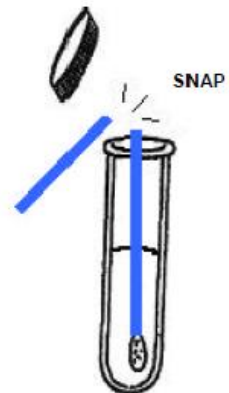
**Step 3.** Open mouth widely and touch the end of the swab to the 5 areas of the throat.



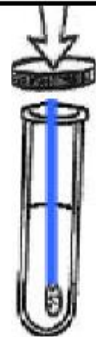
**Step 4.** Uncap tube and keep upright - do not pour out the clear liquid. Place the swab into the tube.



**Step 5.** Align the score line with the top edge of the tube and carefully break the shaft of the swab.



**Step 6.** Place cap back on the test tube and tighten (do not puncture the foil).



**Step 7.** Throw away wrapper and unused swab.

**Step 8.** Wash your hands thoroughly.

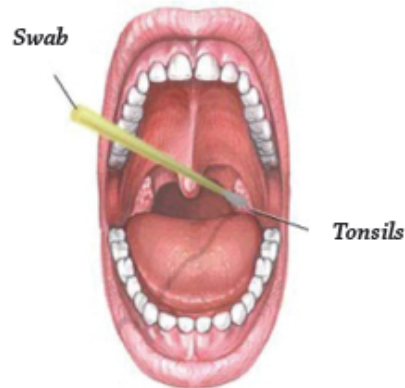


**Step 9.** Return the tube to your health care provider.

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## Attachment C – Self Collection of Pharyngeal and Rectal Swab



### Self-Throat Exam

#### *If you have had a penis in your mouth...*

1. Wash hands with soap and water.
2. Making sure not to touch the cotton tip, remove the swab from the wrapper.
3. Hold in your hand and look into a mirror,
4. Open your mouth wide and wipe the swab around the tonsils on both sides of the throat several times,
5. Do not touch the tongue or cheeks with the swab.
6. Unscrew the cap of the tube making sure not to spill any liquid.
7. Placing the swab into the tube, bend the shaft of the swab until it breaks.
8. Screw the cap of the tube back on tightly,
9. Wash hands again with soap and water.

## Self Test Instructions

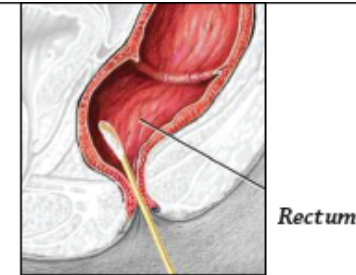
### Auto-Examen Muestra Faríngea

#### *Si has colocado un pene en la boca...*

1. Lavarse las manos con agua y jabón.
2. Sacar el hisopo de algodón del contenedor.
3. Sostener en su mano mirar en un espejo.
4. Abrir la boca y pasar el hisopo de algodón varias veces alrededor del área de las amígdalas, tocando los dos lados de la garganta.
5. No toque la lengua o las mejillas con el hisopo.
6. Colocar el hisopo en tubo de transporte y cerrar herméticamente.
7. Doblar el hisopo hasta que se rompa la parte que sobra del tubo.
8. Lavarse las manos con agua y jabón.



From Whitman-Walker Health



### Self-Rectal Exam

#### *If you have had a penis in your rectum...*

1. Wash your hands with soap and water. Making sure not to touch the cotton tip, remove the swab out of the wrapper.
2. Put the swab 1 inch into the rectum and rotate it for 5 – 10 seconds.
3. Unscrew the cap of the tube making sure not to spill any liquid. Placing the swab into the tube, bend the shaft of the swab until it breaks.
4. Screw the cap of the tube back on tightly. Wash your hands with soap and water.
5. Return the tube.

### Auto-Examen Anal

#### *Si has colocado un pene en la recto...*

1. Lavarse las manos con jabón y agua.
2. Meta el algodón una pulgada adentro del ano y dele vueltas por 5 a 10 segundos.
3. Remueva la tapa de la probeta. Ponga el algodón en el tubo. Rompa el algodón donde sobra del tubo.
4. Ponga la tapa de regreso y cierre para prevenir un derrame. Lavarse las manos con jabón y agua.
5. Devuelva el tubo.